

**Amendments to the Drawings**

Submitted herewith is a Replacement Sheet bearing Figs. 25, 26, and 27. Figs. 25 and 26 have been amended to include the reference numeral 725.

### **Summary of the Interview**

The Applicants thank Examiner Elizabeth R. MacNeill for the courtesy extended to attorneys Kevin Laurence and Daniel Higgs in a personal interview conducted on October 2, 2008. Pursuant to M.P.E.P. § 713.04, the substance of the interview is recorded hereafter.

#### **Nature of Exhibit/Demonstration**

No exhibits or demonstrations were presented.

#### **Claims**

Claims 1, 6, and 14 were discussed.

#### **Prior Art**

U.S. Patent No. 5,989,220 to Shaw et al. ("Shaw") and U.S. Patent No. 5,458,658 to Sircom ("Sircom") were discussed with respect to claim 1.

#### **Principal Proposed Amendments**

No amendments were proposed with respect to claim 1. The amendments to claims 6 and 14 as set forth above in the listing of claims were discussed.

#### **Principal Arguments**

The combination of Shaw and Sircom fails to render claim 1 obvious, at least because the proposed modification of Shaw would fundamentally change the principle of operation of Shaw. The proposed amendments to claims 6 and 14 clearly define subject matter that is nowhere disclosed in U.S. Patent No. 5,501,675 to Erskine ("Erskine").

#### **Results**

Agreement was reached that claim 1 is not obvious in view of Shaw and Sircom, and that claims 6 and 14 as amended herein are not anticipated by Erskine.

## **REMARKS**

Claims 1-4, 6-14 were pending in the Present Application. By this paper, claims 6 and 14 are amended and claims 2 and 11-13 are cancelled without prejudice or disclaimer. Accordingly, claims 1, 3, 4, 6-10, and 14 remain pending in the Application

### **Drawings**

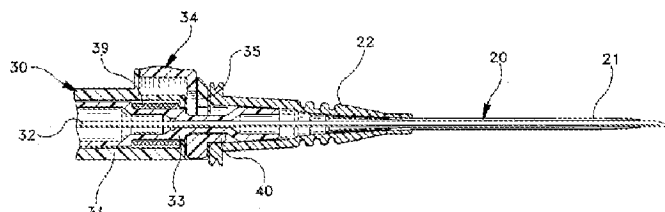
By this paper, each of Figs. 25 and 26 has been amended to include the reference numeral 725, which is recited in line 18 of page 26 of the specification as originally filed. The Applicants respectfully submit that the amendments to the drawings introduce no new matter into the Application.

### **Claim Rejections – 35 U.S.C. § 102**

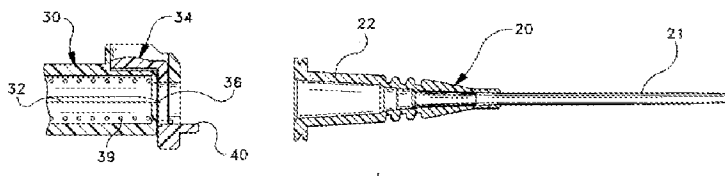
Claims 6-10 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,501,675 issued to Erskine (hereinafter “Erskine”). The Applicants respectfully traverse these rejections. However, in order to expedite prosecution of the Application, independent claims 6 and 14 have been amended.

### **Independent Claims 6 and 14**

The Applicants respectfully submit that Erskine fails to anticipate amended claims 6 and 14 because this reference fails to disclose every element recited in these claims. M.P.E.P. § 2131. For example, Erskine discloses an activation latch 34 that is moved from an “up” position to a “down” position in order permit a needle 32 to be withdrawn into a barrel 31, as depicted in Fig. 2 and Fig. 3 of Erskine (reproduced below).



**Fig. 2 of Erskine**



**Fig. 3 of Erskine**

In the Office Action, it is asserted that Erskine's push surface 34 could feasibly delay retraction of the needle 32 if it were to be maintained in the "up" position, such as by "pulling on the latch." Office Action, page 2. However, movement of Erskine's activation latch 34 radially inwardly from the "up" position to the "down" position causes retraction of the needle 32; it in no way delays or impedes retraction of the needle 32. Accordingly, Erskine fails to disclose "an exposed surface manually operable to move the needle retainer radially inwardly into contact with a wall of the housing to thereby delay retraction of an inserted needle," as recited in amended claim 6, and "selectively manually moving the needle retainer radially inwardly into contact with a wall of the housing to thereby impede retraction of the needle," as recited in claim 14. For at least these reasons, the Applicants respectfully submit that claims 6 and 14 are not anticipated by Erskine and thus respectfully request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

#### Dependent Claims 7-10

Each of claims 7-10 depends from independent claim 6 and thus includes all of the limitations this claim. Therefore, for at least the reasons discussed above with

respect to claim 6, Erskine fails to anticipate claims 7-10. The Applicants thus respectfully request that the rejection of claims 7-10 under 35 U.S.C. § 102(b) be withdrawn

Claim Rejections – 35 U.S.C. § 103

Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 5,989,220 to Shaw et al. (hereinafter “Shaw”) in view of U.S. Patent No. 5,458,658 to Sircom (hereinafter “Sircom”). The Applicants respectfully traverse these rejections.

The Applicants respectfully submit that the foregoing rejections, as set forth in the Office Action, fail to establish a *prima facie* case of obviousness with respect to claim 1. In particular, the modification of Shaw proposed in the Office Action would impermissibly change the principle of operation of this reference. See M.P.E.P. § 2143.01(VI). Moreover, the proposed combination of Shaw and Sircom fails to meet all of the limitations of claim 1.

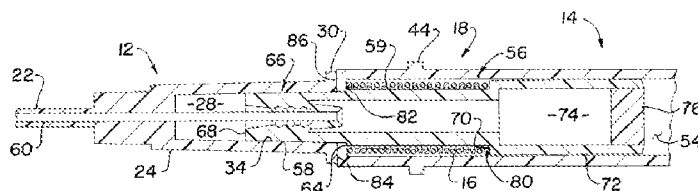
In the Office Action, it is proposed that it would have been obvious to combine the teachings of Shaw and Sircom in order to arrive at a medical device that comprises, *inter alia*,

a needle retainer fixedly connected with the needle and releasably retaining the needle in the extended position, comprising a radially deflecting elongated arm which directly engages the catheter hub;

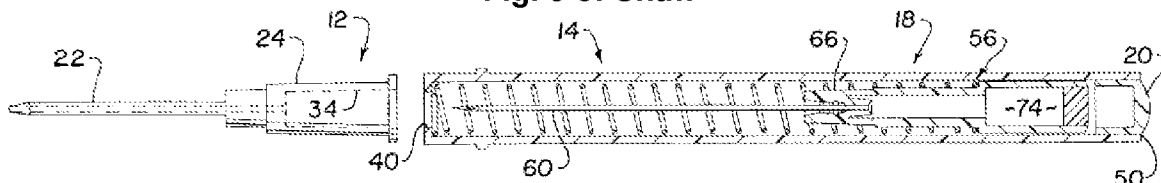
wherein the needle retainer releases the needle upon disengagement of the catheter hub from the elongated arm allowing the elongated arm to deflect inwardly towards the inside of the housing and allowing the biasing element to propel the needle rearward; and

wherein when the needle is in the retracted position, the needle retainer is retracted inside the housing,  
as recited in claim 1. It is asserted that Shaw contains an “arm,” but that this arm is not radially deflecting. In order to cure this deficiency of Shaw, an “arm” is identified in Sircom that is proposed to be radially deflecting. It is then stated that it would have been obvious to use the deflecting arm of Sircom in the place of the arm disclosed in Shaw, yet no indication is provided as to how such a combination would function or otherwise meet the limitations of claim 1.

Shaw discloses a self-retracting catheter introducer assembly 10 that includes a catheter connector 24, a retraction tube 14, and a retraction body 56 connected to a needle 60, as depicted in Fig. 3 and Fig. 4 (reproduced below). As shown in Fig. 3, the catheter connector 24 can be friction fit to the retraction body 56 such that it counteracts the expansion force of a compressed spring. When the catheter connector 24 is removed from the retraction body 56, the compressed spring expands and pushes the retraction body 56 into the retraction tube 14, as shown in Fig. 4. A front portion 58 of the retraction body 56 “which engages the catheter (at 34)” is identified as an arm in the Office Action, but it is noted that the arm is not radially deflecting. Office Action, page 3.

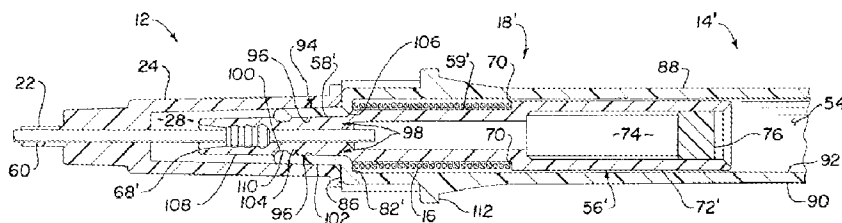


**Fig. 3 of Shaw**

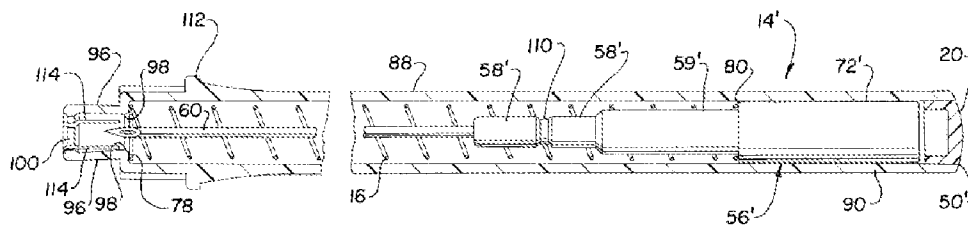


**Fig. 4 of Shaw**

In the Office Action, no mention is made of a second embodiment disclosed in Shaw, which is shown in Fig. 6 and Fig. 9 (reproduced below). The second embodiment includes a catheter connector 24, a retraction tube 14', and a retraction body 56' connected to a needle 60. This embodiment further includes a plurality of arms 96 at the distal end of the retraction body 56' that are biased to "normally spring open" (i.e., are biased to the orientation shown in Fig. 9). The arms 96 include protrusions 100 that fit within a groove 110 in the retraction body 56'. As shown in Fig. 6, the catheter connector 24 can be friction fit to the distal end of the retraction tube 14' such that it causes the protrusions 100 of the arms 96 to seat within the groove 110. As shown in Fig. 9, when the catheter connector 24 is removed from the retraction tube 14', the arms 96 move to their normal, open state and the compressed spring pushes the retraction body 56' into the retraction tube 14'.



**Fig. 6 of Shaw**

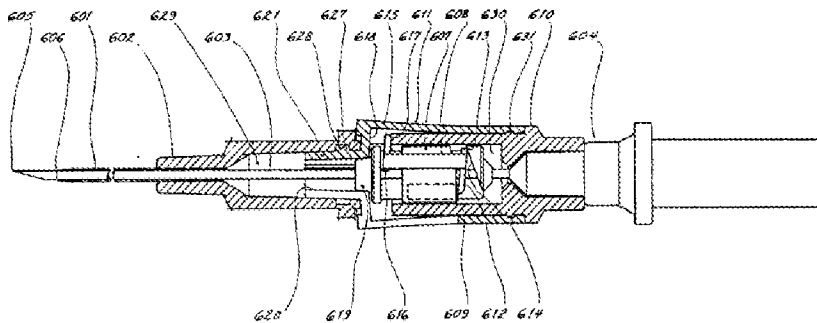


**Fig. 9 of Shaw**

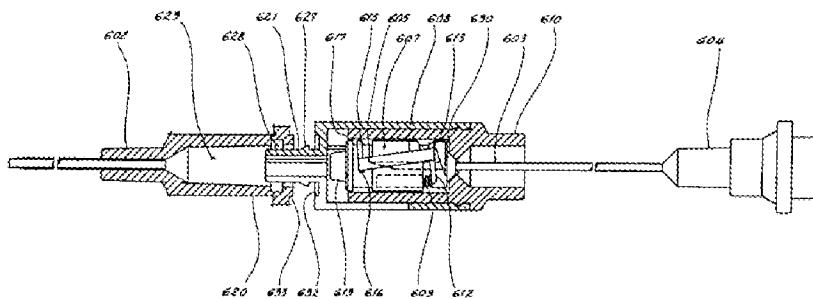
Neither of the retraction bodies 56, 56' disclosed in Shaw comprises a deflecting arm. Moreover, the only movable arms disclosed in Shaw are extensions at a distal end of the retraction tube 14' of the second embodiment. Accordingly, when the needle 60

is retracted into the retraction tube 14', the arms 96 remain at the end of the retraction tube 14'; they are not retracted into the retraction tube 14'.

The needle guard assembly disclosed in Sircom (see Fig. 1 and Fig. 6, reproduced below) operates in a very different manner from the embodiments disclosed in Shaw. For example, in Sircom, the retraction of a needle 603 into an outer shell 607 permits the removal of a catheter hub 602 from the outer shell 607. This is completely different from the embodiments of Shaw, in which it is the removal of the catheter connector 24 hub that permits retraction of the needle 60 into the retraction tube 14, 14'.



**Fig. 1 of Sircom**



**Fig. 6 of Sircom**

In view of the foregoing discussion, it is unclear how the "deflecting arm of Sircom" could be used in the place of "the frictional engagement of Shaw," as proposed in the Office Action. Office Action, page 4. To make such a modification would fundamentally alter the principal of operation of Shaw. Indeed, the teachings of Shaw



and Sircom are incompatible at least with respect to the timing and conditions for removal of a catheter hub from a needle protection assembly.

Moreover, the combination of Shaw and Sircom fails to disclose all of the limitations of claim 1. For example, neither Shaw nor Sircom discloses a needle retainer fixedly connected with the needle comprising a radially deflecting elongated arm which directly engages a catheter hub. Additionally, neither Shaw nor Sircom discloses that, when the needle is in the retracted position, the needle retainer is retracted inside the housing.

Therefore, the Applicants respectfully submit that claim 1 is not obvious in view of Shaw and Sircom and request that the rejection of this claim under 35 U.S.C. § 103 be withdrawn. Moreover, since claims 3 and 4 depend from claim 1, these claims also are not obvious in view of Shaw and Sircom. See M.P.E.P. § 2143.03. The Applicants thus request that the rejection of claims 3 and 4 under 35 U.S.C. § 103 be withdrawn.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the applicants submit that the claims define patentable subject matter and a Notice of Allowance is respectfully requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the Applicants' attorney at the address or telephone number given herein.

Dated this 13th day of October, 2008.

Respectfully submitted,

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